

REMARKS

Reconsideration of this application is respectfully requested. Claim 6 has been canceled with out prejudice. Claims 18 and 19 have been added. Claims 18 and 19 are similar to claims 9 and 10, but include the transitional phrase "consisting of". Claims 5, 9-14, 16, 18, and 19 are pending and at issue.

Claims 5, 6, and 9 have been rejected under 35 U.S.C. §102(b) as anticipated by Weiner (U.S. Patent No. 5,200,393).

Weiner discloses a lipid excipient to be used in pharmaceutical or cosmetic preparations (see abstract of Weiner). Weiner only discloses insulin formulations for nasal and mucosal delivery. See, for example, the abstract ("For example, the lipid excipient in sprayable or droppable form has special utility in the non-irritating delivery of peptides (e.g., calcitonin and insulin) to the nasal mucosa, due to the ability of the excipient to enhance absorption across nasal membranes") and claim 1 of Weiner. The only exemplified formulations including insulin in Weiner are those in Examples 4 and 6-8. The formulations in Examples 4, 6, and 8 were intranasally administered. The formulation in Example 7 was surgically instilled in rats. Weiner, therefore, does not disclose or suggest the topical administration of insulin let alone topical administration of insulin for increasing skin firmness and the other indications recited in the pending claims.

In the July 21, 2003 Office Action, the Examiner refers to column 7, lines 9-16, of Weiner, which discloses that "[w]hen [the lipid excipient] is used as a

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cosmetic preparation, the lipid excipients can be applied to the skin alone or in combination with biologically active or other agents (e.g., such as perfumes, paraffins, oils, coloring agents, glycerins) to improve the surface characteristics ..." (emphasis added). Weiner, however, does not disclose or suggest using Insulin in a cosmetic preparation. Rather, Weiner emphasizes the use of his lipid excipients for Intranasal delivery of insulin as discussed above.

For the foregoing reasons, Weiner fails to anticipate claims 5 and 9, and this rejection should be withdrawn.

Claim 6 has been rejected under 35 U.S.C. §102(e) as anticipated by Danilelov (U.S. Patent No. 5,885,974).

Claim 6 has been canceled without prejudice. Therefore, this rejection is moot."

Claims 5, 6, and 9-17 have been rejected as under 35 U.S.C. §102(b) as anticipated by Hinson (U.S. Patent No. 5,145,679).

This rejection is respectfully traversed and reconsideration is respectfully requested.

Hinson discloses administering a mixture of glucose and Insulin to treat skin lesions, skin ulcers and other skin maladies. See the abstract of Hinson. The skin lesions, ulcers and maladies are a pathologic result caused by diabetes, phlebitis, or other circulatory problems (see col. 1, lines 19-35 of Hinson).

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In contrast, the method of the presently claimed invention includes applying the composition of the present invention to skin or scalp, not skin lesions, skin ulcers, or skin maladies. Applicants respectfully submit that skin lesions, skin ulcers, and skin maladies as defined in Hinson are not skin.

Furthermore, Hinson does not provide any motivation for treating physiological changes in skin such as those recited in the pending claims. Rather, Hinson only teaches treating pathological changes in the skin, such as the formation of skin lesions and skin ulcers, with a mixture of insulin and glucose. Hinson also does not provide a reasonable expectation that the compositions of the presently claimed invention would be able to treat physiological changes in skin such as those recited in the pending claims.

Hinson does not disclose or suggest treating aging of skin or scalp or preventing skin or scalp from aging with a composition *consisting of* at least 2 units of insulin, which can be natural, synthetic, recombinant, human or animal, per 100 g of composition as recited in claim 18. Nor does Hinson disclose or suggest increasing skin firmness and elasticity, reducing lines and wrinkles of skin, improving age spots and clarity of skin, raising ability of skin or scalp to scavenge oxygen free radicals, raising ability of skin or scalp against UV-induced damage, treating aging of skin or scalp, preventing skin or scalp from aging, treating winter itch, or improving secretion of sebaceous and sweat glands with a composition *consisting of* at least 2 units of insulin, which can be natural, synthetic, recombinant, human or animal, per 100 g of

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composition as recited in claim 19. All of the formulations disclosed in Hinson include glucose, which is not encompassed by claims 18 and 19.

For the foregoing reasons, Hinson does not anticipate claims 6, 9-14, 16, 18, and 19 and this rejection should be withdrawn.

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted



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